



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0155]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0363. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Veterinary Food Directive

OMB Control Number 0910-0363--Extension

Section 504 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 354) establishes a regulatory category for certain new animal drugs called veterinary feed directive (VFD) drugs. The VFD regulation is set forth at § 558.6 (21 CFR 558.6). VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice (§ 558.6(b)(6)). An animal feed containing a VFD drug or a combination VFD drug may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian (§ 558.6(a)(1)).

Veterinarians issue three copies of the VFD: one for their own records, one for their client, and one to the client's VFD feed distributor (§§ 558.6(a)(4) and 558.6(b)(8)-(9)). The VFD includes information about the number and species of animals to receive feed containing one or more of the VFD drugs (§ 558.6(b)(3)), along with other information required under § 558.6. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute such feed and must maintain records of the receipt and distribution of all medicated feeds containing VFD drugs.

The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost effectively as possible. The VFD regulation is tailored to the unique circumstances relating to the distribution and use of animal feeds containing a VFD drug.

We use the information collected to assess compliance with the VFD regulation. The required recordkeeping and third party disclosures provide assurance that the medicated feeds will be safe and effective for their labeled conditions of use and that edible products from treated animals will be free of unsafe drug residues.

We are retaining the estimates used in FDA’s analysis of the information collection provisions in the final rule entitled “Veterinary Feed Directive,” published in the *Federal Register* of June 3, 2015 (80 FR 31708 at 31728), and approved by OMB.

A. Reporting Requirements

Description of Respondents: VFD Feed Distributors and VFD Drug Sponsors.

A distributor of animal feed containing a VFD drug must notify FDA prior to the first time it distributes the VFD feed (§ 558.6(c)(5)). This notification is required one time per distributor and must include the information set forth in § 558.6(c)(5). In addition, a distributor must notify FDA within 30 days of any change in ownership, business name, or business address (§ 558.6(c)(6)). Additional reporting burdens for current VFD drug sponsors are approved under OMB control numbers 0910-0032 (New Animal Drug Applications) and 0910-0669 (Abbreviated New Animal Drug Applications).

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
558.6(c)(5) requires a distributor to notify FDA prior to the first time it distributes a VFD feed	300	1	300	0.125 (7 minutes)	37.5
558.6(c)(6) requires a distributor to notify FDA within 30 days of any change in ownership, business name, or business address	20	1	20	0.125 (7 minutes)	2.5
Total					40

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

B. Recordkeeping Requirements

Description of Respondents: VFD Feed Distributors, Food Animal Veterinarians, and Clients (Food Animal Producers).

As stated previously, veterinarians issue three copies of the VFD: one for their own records, one for their client, and one to the client's VFD feed distributor. All involved parties (veterinarian, distributor, and client) must retain a copy of the VFD for 2 years (§ 558.6(a)(4)). In addition, VFD feed distributors must also keep receipt and distribution records of VFD feeds they manufacture and make them available for inspection by FDA for 2 years (§ 558.6(c)(3)). If a distributor manufactures the VFD feed, the distributor must also keep VFD manufacturing records for 1 year in accordance with 21 CFR part 225 and such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910-0152, "Current Good Manufacturing Practice Regulations for Medicated Feed." Distributors may distribute VFD feeds to another distributor only if the originating distributor first obtains a written acknowledgement letter. Such letters, like VFDs, are also subject to a 2-year record retention requirement (§ 558.6(c)(8)).

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
558.6(a)(4); required recordkeeping by veterinarians and producers	13,050	114.9	1,500,000	0.0167 (1 minute)	25,050
558.6(a)(4), (c)(3), (c)(4), and (c)(8); required recordkeeping by distributors	1,376	545.1	750,000	0.0167 (1 minute)	12,525
Total					37,575

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

C. Third-Party Disclosure Requirements

Description of Respondents: VFD Drug Sponsors, Food Animal Veterinarians, VFD Feed Distributors, and Clients

FDA regulation requires that veterinarians include the information specified at § 558.6(b)(3) through (5) on the VFD. Additional requirements relating to the VFD are specified at § 558.6(b)(7) through (9). A distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgement letter from the receiving distributor (consignee) before the feed is shipped (§ 558.6(c)(8)).

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

21 CFR Section/Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
558.6(b)(3)-(b)(5) and (b)(7)-(b)(9); required disclosures when a veterinarian issues a VFD	3,050	246	750,000	0.125 (7 minutes)	93,750
558.6(c)(8); required disclosure (acknowledgement letter) from one distributor to another	1,000	5	5,000	0.125 (7 minutes)	625
Total					94,375

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The VFD regulation also contains several labeling provisions that are exempt from OMB review and approval under the PRA because they are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and therefore do not constitute a “collection of information” under the PRA (44 U.S.C. 3501, *et seq.*). All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: “Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian” (§ 558.6(a)(6)). In addition, the veterinarian must ensure that the following statement is included on the VFD (§ 558.6(b)(3)(xiii)): “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.”

The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD drug(s) along with one or more over-the-counter animal drugs in an approved, conditionally approved, or indexed combination VFD drug (§ 558.6(b)(6)). The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

1. “This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs” (§ 558.6(b)(6)(i)).

2. “This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.” (List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.) (§ 558.6(b)(6)(ii)).

3. “This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component” (§ 558.6(b)(6)(iii)).

These labeling statements are not subject to review by OMB because, as stated previously, they are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and therefore do not constitute a “collection of information” under the PRA (44 U.S.C. 3501, *et seq.*).

The one-time burdens included in FDA’s analysis of the June 3, 2015, final rule (80 FR 31708 at 31729 to 31732) are not included in the estimate provided in this notice. FDA’s estimate of the annual recurring burden for this information collection has not changed since the last OMB approval.

Dated: June 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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